

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/B2004/002668

International filing date (day/month/year)
16.08.2004

Priority date (day/month/year)
25.08.2003

International Patent Classification (IPC) or both national classification and IPC
B30B15/06

Applicant
ALPEX PHARMA SA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/002668

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/B2004/002668

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

6-8,12-14

No: Claims

1-5,9-11,15-19

Inventive step (IS)

Yes: Claims

1-19

No: Claims

Industrial applicability (IA)

Yes: Claims

1-19

No: Claims

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
D1: WO-A-9958320 (FUISZ TECHNOLOGIES LTD) 18 November 1999 (1999-11-18)
D2: EP-A-0513890 (GEN MOTORS CORP) 19 November 1992 (1992-11-19)
D3: DE-A-10046869 (HENKEL KGAA) 18 April 2002 (2002-04-18)
D4: US-A-6106267 (AYLWARD JOHN T) 22 August 2000 (2000-08-22)
D5: GB-A-2276345 (UNILEVER PLC) 28 September 1994 (1994-09-28)
2. The following is stated under reference to point VIII of this communication.
 - 2.1 It is mentioned that features which do not comply with Article 6 PCT cannot be used for distinguishing over the prior art in order to assess novelty in the sense of Article 33(2) PCT or inventive step in the sense of Article 33(3) PCT.
 - 2.2 The document D1 discloses, cf abstract and figures 1-10 (the references in parentheses applying to this document):
a tablet punch (40) comprising a punch cup having a non-stick polymeric coating (50) applied thereto.
Consequently **the subject matter of claim 1 lacks novelty** and claim 1 does not meet the requirements of Article 33(2) PCT.
 - 2.3 The documents D2, D3, D4 and D5 disclose also the subject matter of claim 1.
 - 2.4 The document D1 discloses:
a method for manufacturing compressed forms comprising the step of compressing an amount of a composition in a tablet press between an opposing pair of tablet punches (40, 42) where the punch cups of said punches have a non-slick polymeric coating (50).
Consequently the subject matter of claim 9 lacks novelty and claim 9 does not meet the requirements of Article 33(2) PCT.
 - 2.5 The documents D2, D3, D4 and D5 disclose also the subject matter of claim 9.

- 2.6 The document D1 discloses, cf. page 9, lines 19-22:
a compressed tablet which consists of an active ingredient and non lubricating tablet excipients.
Consequently the subject matter of claim **19** lacks novelty and claim **19** does not meet the requirements of Article 33(2) PCT.
- 2.7 The documents D2, D3, D4 and D5 disclose also the subject matter of claim **9**.
3. Dependent claims **2-8 and 10-18** do not appear to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step.
The features of dependent claims **5 and 15-18** have already been employed in the apparatus disclosed in D1, cf page 19, line 29 - page 20, line 2 and figures 11-15.
The features of dependent claims **2, 3, 6, 7, 10, 11, 13 and 14** have already been employed in the apparatus disclosed in D2, cf claims 4 and 5.
The features of dependent claims **4 and 8** have already been employed in the apparatus disclosed in D3, cf claims 19.
5. Claims 1-19 meet the requirements of Article 33(4) PCT.

Re Item VII

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.
2. Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT.
3. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

1. The following is observed in respect of Article 6 PCT.
 - 1.1 Claims **1 and 5** have been drafted as separate independent claims of the apparatus category. They contain the non corresponding features "coating applied" and "lathed head affixed". Under reference to PCT Guidelines 5.15 and 5.33 both features cause a non-compliance with Article 6 PCT. For the benefit of the procedure in this written opinion, claim **5** has been considered dependent of claim **1** with the characterizing part being "the coating being on a lathed head affixed thereto"
 - 1.2 Similar is applicable to independent claims **9 and 12**.
 - 1.3 The expression "non-stick" used in claims **1-5, 9, 12-14** causes further unclarity of the claimed matter because it refers to the function of the layer once the punch is in use. It is to be remarked that the non sticking feature is determined by the interaction of the coating with an entity not being part of the matter as claimed by claim **1**, see also PCT Guidelines 5.37.
 - 1.4 The expression "consisting" in claim **19** is considered as a "closed" type of transition phrase, cf PCT Guidelines 5.24(a).
 - 1.5 The expression "non-lubricating" in claim **19** defines the subject matter by means of negative features, cf PCT Guidelines 5.41 and it renders the subject matter of the claim **19** unclear.